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10/591,452	07/02/2007	Peter Mulleijans	2003048-US	1473
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COLOPLAST A/S			EXAMINER	
Attention: Corporate Patents			CHAPMAN, GINGER T	
Holtedam 1				
DK-3050 Humleback,			ART UNIT	
DENMARK			PAPER NUMBER	
			3761	
			NOTIFICATION DATE	
			DELIVERY MODE	
			09/16/2010	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/591,452

Applicant(s)

MULLEJANS ET AL.

Examiner

Ginger T. Chapman

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2010.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
4a) Of the above claim(s) 15-17 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-14 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 01 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/GS-08)
Paper No(s)/Mail Date 08/06/2007
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-14 in the reply filed on 11 March 2010 is acknowledged.

Claims 15-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11 March 2010.

Status of the Claims

Claims 1-17 are pending in the application, claims 15-17 are withdrawn from consideration as being drawn to a nonelected invention, claims 1-14 are examined on the merits.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 206, see paragraph [0039], Figure 10.

The drawings are objected to as failing to comply with 37 CFR 1.84(l) because all drawings must be made by a process which gives them satisfactory reproduction characteristics. Every line, number, and letter must be durable, clean, black, sufficiently dense and dark, and uniformly thick and well-defined. The weight of all lines and letters must be heavy enough to permit adequate reproduction. This requirement applies to all lines however fine, to shading, and to lines representing cut surfaces in sectional views. Lines and strokes of different thicknesses may be used in the same drawing where different thicknesses have a different meaning.

(l) Character of lines, numbers, and letters. **All drawings must be made by a process which will give them satisfactory reproduction characteristics.** Every line, number, and letter must be durable, clean, black (except for color drawings), sufficiently dense and dark, and uniformly thick and well-defined. The weight of all lines and letters must be heavy enough to permit adequate reproduction. This requirement applies to all lines however fine, to shading, and to lines representing cut surfaces in sectional views. Lines and strokes of different thicknesses may be used in the same drawing where different thicknesses have a different meaning.

(p) Numbers, letters, and reference characters.

(1) Reference characters (numerals are preferred), sheet numbers, and view numbers must be plain and legible, and must not be used in association with brackets or inverted commas, or enclosed within outlines, e.g., encircled. They must be oriented in the same direction as the view so as to avoid having to rotate the sheet. Reference characters should be arranged to follow the profile of the object depicted.

(3) Numbers, letters, and reference characters must measure at least .32 cm. (1/8 inch) in height. They should not be placed in the drawing so as to interfere with its comprehension. Therefore, they should not cross or mingle with the lines. They should not be placed upon hatched or shaded surfaces. When necessary, such as indicating a surface or cross section, a reference character may be underlined and a blank space may be left in the hatching or shading where the character occurs so that it appears distinct.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet"

pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 8 is objected to because of the following informalities: line 3 recites, "on outlet", the examiner is considering this a typographical error of "an outlet". Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 1) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "the patient's body" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

- 1) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 9, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferguson et al (US 5,306,264).

With respect to claim 1, as best depicted in Figures 3, 5 and 6, Ferguson discloses an ostomy system for receiving bodily waste, comprising:

a drainage bag (figs. 1 and 2;

at least one filter (fig. 3 at 10) comprising a foam 44, 70 (column 3, lines 61-63 and column 4, lines 20-21) for preventing liquid and solid particles from passing from the drainage bag to its surroundings (column 5, lines , the foam defining a passageway for releasing flatus gasses from the drainage bag to its surroundings;

characterised in that

at least a portion of the foam 70 is arranged at a folding line (figs. 5 and 6) defined by the drainage bag during use thereof.

The examiner notes that the instant Specification, in particular at PG-Publication paragraphs [0010, 0014, 0019, 0037-8], Figures 4A and 6, indicates that the “folding line” occurs naturally by folding of the bag caused by the wearer’s movements, i.e. when the user sits, lies down, stands up or generally moves about, the motion of the wearer causes the bag to fold naturally with the wearer’s movements, that one or more folding lines can occur along any parts of the bag that caused by wearer movements; and thus the folding line is not a structural component of the pouch since the pouch can be folded along any number of lines caused by the bag moving in response to the movements of the wearer. The instant Specification states that folding lines often intersect the areas located about the coupling system or the inner bag where the pouch is attached to the wearer. Ferguson discloses the filter located about the coupling

system and the inner bag, Ferguson, at column 5, lines 2-4, discloses that the body motion by the wearer acts upon the filter in the same manner as disclosed in the instant Specification at [0010], and thus discloses that at least a portion of the foam is arranged at a folding line defined by the drainage bag during use thereof and thus meets the claim.

With respect to claim 2, Ferguson discloses the filter (figs. 3, 5 and 6) defines a filter inlet 78, 80 (figs. 3, 5, 6) facing the interior of the drainage bag (column 4, lines 55-61) and flatus gas outlet 36 (fig. 3) facing the surroundings of the bag (column 5, lines 19-22), and wherein the folding line (figs. 5, 6; the folding line is considered to be the area of the bag at the coupling system and the areas adjacent to and surrounding the area where the coupling system is located where the bag will fold naturally during body movements and motion of the wearer, and any area where the bag will fold naturally due to movements of the wearer) intersects the filter inlet 78, 80.

With respect to claim 3, Ferguson discloses the filter (figs. 3, 5 and 6) defines a filter inlet 78, 80 (figs. 3, 5, 6) facing the interior of the drainage bag (column 4, lines 55-61) and flatus gas outlet 36 (fig. 3) facing the surroundings of the bag (column 5, lines 19-22), and wherein the folding line (figs. 5, 6; the folding line is considered to be the area of the bag at the coupling system and the areas adjacent to and surrounding the area where the coupling system is located where the bag will fold naturally during body movements and motion of the wearer, and any area where the bag will fold naturally due to movements of the wearer) intersects the filter inlet 78, 80.

With respect to claim 4, Ferguson discloses a coupling system 30 for securing the bag in relation to a stoma of a patient, the coupling system 30 defining an orifice to enable bodily waste to be received by the drainage bag (column 3, lines 43-50).

With respect to claim 9, Ferguson discloses said passageway 10 (fig. 3) further extends through a gas permeable membrane (column 4, lines 14-19).

With respect to claim 12, Ferguson discloses the drainage bag is of a structure which essentially maintains its physical integrity upon immersion in water (column 3, lines 31-33; column 7, lines 39-40).

With respect to claim 14, Ferguson discloses wherein the at least one filter comprises a plurality of filters 40, 70 (fig. 3); 40, 146 (figs. 9 and 10), at least a portion of at least one of the filters being arranged at a folding line defined by the drainage bag during use thereof (see claim 1 for detailed analysis of the folding line).

Claim Rejections - 35 USC § 103

- 1) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 2) The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferguson in view of Broida (US 5,013,307).

With respect to claims 5 and 10, Ferguson discloses the claimed invention except for the filter is arranged between the coupling system and the drainage bag (**claim 5**); and wherein the coupling system is connected to the filter flange along a contact area, whereby the attachment zone is radially displaced with respect to the contact area (**claim 10**). Ferguson discloses the filter is located adjacent the coupling system at a location that ensures that the outward flow of flatus gases passes through the filter; the filter 70 constitutes a filter flange 72 (fig. 3), and wherein the drainage bag is connected to a first surface of the filter flange 72 along an attachment zone (figs. 5 and 6), thus providing motivation for such (column 1, lines 12-14).

Broida, at column 4, lines 23-40, and column 2, lines 20-23 and lines 40-43, teaches that leaks often occur at the top of ostomy flanges where attached to wearer's skin and provides motivation for an odor absorbing filter arranged between the coupling system and the drainage bag to absorb odor. As best depicted in Figures 2 and 3, Broida teaches filter 10 arranged between coupling system 23 and drainage bag 20 (claim 5); the filter 10 constitutes a filter flange 10, the drainage bag 20 is connected to a first surface of the filter flange 10 along an attachment zone 12, and wherein the coupling system 23 is connected to the filter flange 10 along a contact area A (fig. 3), whereby said attachment zone 12 is radially displaced with respect to said contact area (column 2, lines 20-23). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the filter of Ferguson arranged between the coupling system and drainage bag as taught by Broida since both locations perform the same

function and it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Claims 6-7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferguson in view of Petersen (US 4,826,495).

With respect to claims 6-7, Ferguson discloses the claimed invention except for wherein the filter is provided in the coupling system (**claim 6**); said surroundings of the drainage bag is constituted by an outer bag which is secured in relation to the patient's body and in relation to the drainage bag by means of said coupling system (**claim 7**). Ferguson discloses the drainage bag is impermeable to flatus gases, thus providing motivation for such (column 3, lines 31-33). Ferguson discloses the filter is located adjacent the coupling system at a location that ensures that the outward flow of flatus gases passes through the filter, thus providing motivation for such (column 1, lines 12-14).

Petersen provides motivation for a filter at a location that the outward flow of flatus gas passes through the filter (column 1, lines 13-15). As best depicted in Figures 2, 3 and 5, Peterson teaches the filter 36 is provided in 34 the coupling system 10 (column 5, lines 42-45); the drainage bag 40 is surrounded by an outer bag 46 which is secured in relation to the patient's body and in relation to the drainage bag by means of the coupling system (fig. 5; column 7, lines 7-8). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the filter of Ferguson arranged between the coupling system and drainage bag as taught by Petersen since both locations perform the same function and it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

With respect to claim 13, Ferguson discloses the claimed invention except for expressly disclosing the coupling system includes means for forcing the flow of flatus gases along a predetermined passageway. Ferguson discloses the filter includes means for forcing the flow of flatus gases along a predetermined passageway through the filter, thus providing motivation for such (column 2, lines 30-35, lines 51-53). Petersen teaches the coupling system 10 includes means 30, 32 for forcing the flow of flatus gases along a predetermined passageway 38 (column 6, lines 11-13; column 2, lines 32-34 and lines 47-48) through the filter. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the coupling system means of Petersen for the system of Ferguson since both means force the flow of flatus gases along a predetermined passageway in the same manner wherein the only difference is the location of the means in the coupling system comprising the filter or in the filter itself since both locations perform the same function and it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ferguson in view of Petersen (US 4,826,495) as applied to claim 7 above, and further in view of Smith et al (US 5,690,622).

With respect to claim 8, the combination of Ferguson and Petersen discloses the claimed invention except for a flatus filter for releasing flatus gases from the outer bag. Petersen discloses the outer bag is essentially made from a material which is impermeable to flatus gasses and comprises an outlet for releasing flatus gases from the outer bag, thus providing motivation for such (column 7, lines 39-41), but does not disclose a flatus filter for releasing flatus gases from the outer bag. As best depicted in Figure 2, Smith discloses an outer bag 2 made from a

material impermeable to flatus gases and comprises an outlet 18 covered by a flatus filter 19 for releasing flatus gases from the outer bag (column 3, lines 26-27 and line 56 to column 4, lines 1-11). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the filter for the outer bag as taught by Smith for the ostomy system of Ferguson and Peterson since Smith states, at column 4, lines 13-20, that the benefit of forming the system with this design is that flatus that passes from the inner bag to the outer bag is deodorized before passing into the surrounding atmosphere.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ferguson in view of Broida as applied to claim 5 above, and further in view of Johnsen et al (US 5,085,652).

With respect to claim 11, the combination of Ferguson and Broida disclose the claimed invention except for the closed cell foam. Ferguson discloses the foam is an open-cell foam and the filter constitutes a filter flange 72 (fig. 3) in which the open cell foam is supported by the flange, thus providing motivation for such. As best depicted in Figure 5, Johnsen teaches the foam 30 is an open-cell foam, the filter 30 constitutes a filter flange 20, in which the open cell foam is supported by a closed cell foam 36 (column 5, lines 43-45 and lines 61-63). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the closed cell foam of Johnsen for the flange of Ferguson and Broida since Johnsen states at column 5, lines 66-68 to column 6, lines 1-2, that the benefit of forming the filter with this design is that the closed cell foam supports the open-cell foam filter and makes the filter flange easier to handle, apply and remove.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lesko (US 5,643,234) Figures 5, 6; Pedersen (US 2007/0027434 A1) Figures 2, 4A; Jensen (US 5,591,447) Figures 9 and 10.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/
Examiner, Art Unit 3761
09/09/10

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772

